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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

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☑ *Additional inventors are being named on the ___ separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

METHOD AND DEVICE FOR PILL DISPENSING

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ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 4

☑ Drawing(s) *Number of Sheets* 4

☐ Application Data Sheet. See 37 CFR 1.76

☐ CD(s), Number

☑ Other (specify) EXHIBIT A (16 pp.)

METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check or money order is enclosed to cover the filing fees

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: ______

Respectfully submitted,

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Docket Number: 434-293P

USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

PROVISIONAL APPLICATION COVER SHEET
Additional Page

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Docket Number	434-293P	Type a plus sign (+) inside this box →	+

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Docket No. 434-293P

METHOD AND DEVICE FOR PILL DISPENSING

This is a PROVISIONAL application filed under 35 U.S.C. Section 111(b) and in compliance with the requirements of 35 U.S.C. Section 112.

TECHNICAL FIELD

The present invention relates generally to a method and device for pill dispensing and, in particular, to a pill dispenser and method of pill dispensing that will dispense pills no faster than a prescribed rate.

BACKGROUND OF THE INVENTION

Schedule II narcotics as well as other medications are addictive and often abused by patients who may take the medication more frequently than their prescribed rate. For this reason, physicians are often reluctant to prescribe them. While many types of pill dispensers are known in the art, none limit pill dispensing to a prescribed rate.. Additionally, no pill dispenser exists for reducing the chance for patient abuse of prescribed medication if the patient attempts to take the medication at a more frequent rate than

prescribed. Therefore, the need exists for a dispenser that dispenses pills no faster than a prescribed rate. Additionally, the need exists for a dispenser that also detects tampering with the dispenser and, in the event of user tampering, renders the pills impotent thereby reducing the chance of abuse by the patient. Additional aspects, advantages and other novel features of the invention will be set forth in part in the description that follows and in part will become apparent to those skilled in the art upon examination of the foregoing or may be learned with the practice of the invention.

DESCRIPTION OF THE INVENTION

In one aspect, the present invention, as shown in Exhibit A (incorporated herein by reference) appended hereto, provides for a method and device for pill dispensing such that pills are supplied to a user at a prescribed rate and attempts by the patient or other individual to increase the rate results in rendering the pills impotent.

The invention comprises a pill container that remains normally in a locked position preventing user access to the medication, but allows the user to rotate a lever or cap to release the pill at the scheduled time. In one embodiment, the container includes an exterior shell, an internal pill chamber, a pill advancer, electronics, and a tamper detection sensor. The outer shell provides a sealed container and may include at least one opening where the pill becomes released. The pill advancer may include a lever through the side

of the container, a ring that rotates around the exterior shell, or any mechanism suitable for releasing a single pill at a prescribed time.

A mechanical or electrical check stops the advancer if it does not detect the presence of a pill. The advancer locks in place by use of a mechanical pin controlled by the electronics system. The pin defaults to a position thereby locking the advancer in a release position. The pin will only unlock after a prescribed amount of time passes. In one embodiment, the prescribed amount of time corresponds to a prescribed time period established by a doctor. For example, the doctor may prescribe one pill every four hours. Therefore, the pin will only unlock after this amount of time passes. Alternatively, a pharmaceutical manufacturer may preload a pill dispenser with the pills and provide a security code for activation of the prescribed time period at the local pharmacy prior to patient use. The pin may operate similarly to the mechanism of a gun and will "fire" back into the locked position when a pill becomes released.

An internal pill chamber stores the pills in the dispenser. The internal pill chamber may be divided into two or more divisions. In one embodiment, the internal pill chamber includes a lower half and upper half. The lower half stores the pills and includes a chute to direct the pills toward the pill advancer. The upper half contains solvent such that the solvent may become released into the pill chamber if the pill container detects a user tampering with the device. The solvent may be any compound that renders the pill

impotent such as by chemical reaction with the active agent in the pill. Additionally, the solvent may vary in composition depending on the type of prescription. A spring and plunger assembly may provide pressure on the solvent and, due to the solvent being under pressure, allow for rapid solvent release. In one embodiment, the pill dispenser may include actuators to activate the mechanisms to release a pill and to destroy the pills in the case of tampering. The pill dispenser may also include sensors for detection of when a user takes a pill from the dispenser and if a user tampers with the container. The sensors may detect tampering such as user attempts to melt, cut, crush, freeze, microwave, or other possible user attacks on the pill dispenser. A microcontroller may control the actuators and read the sensors.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise form disclosed. Obvious modifications or variations are possible in light of the above teachings. The embodiment was chosen and described to provide the best illustration of the principles of the invention and its practical application to thereby enable one of ordinary skill in the art to utilize the invention in various embodiments and with various modifications as are suited to the particular use contemplated. All such modifications and variations are within the scope of the invention as determined by the foregoing description and appended claims when interpreted in accordance with the breadth to which they are fairly, legally and equitably entitled.

EXHIBIT A

Introduction

Schedule II narcotics are addictive and often abused by patients who may take them more frequently than their prescribed rate. For this reason, physicians are often reluctant to prescribe them. The goal of this project is to design a container that will dispense pills no faster than the prescribed rate, reducing the chance for abuse. Furthermore, the container will use a sensor to detect tampering, and in the event the container is opened by the user, it will release a solvent rendering the pills impotent.

This document describes several designs for the electronics that control pill release, detect tampering, and actuate the pill deactivation mechanism. It covers basic system requirements and describes several implementation options.

Requirements

The electronics must interface with mechanisms to control the release of pills, detect tampering, and deactivate the pills if tampering is detected. Moreover, the electronics should be small enough to fit into a reasonable size container, consume little power, and be affordable.

Pill Delivery

A pill is said to be *released* or *available* if the container will provide a pill when the user reequests one. If the user requests a pill before one is available, the container should indicate that no pill is available. The device should release pills at the *prescribed rate*, the rate prescribed the patient's physician. The *prescribed interval*, the amount of time between each pill as prescribed by the physiscian, is often used in place of the prescribed rate. Typical rates are one pill every four hours to one pill every twelve hours. The algorithm used to allow the patient to take pills must take into account that the patient might not take pills at precisely the prescribed time.

Pill deactivation

When tampering is detected the electronics must actuate a mechanism that destroys the pill's narcotic effect. The pills are said to be destroyed once they no longer have narcotic effect, even if they retain part or all of their original shape.

Tamper detection

The device must detect whether someone attempts to tamper with it so it can render the pills impotent. We call such attempts *attacks* on the container. Attacks on the device include attempts to cut, crush, or drill holes through the container to remove the pills inside. The device should be able to resist these attacks. Other forms of attack include attempting to melt the container, either with heat or chemicals, and freezing or microwaving the device in an attempt to destroy the electronics. Though the device cannot be designed to prevent every imaginable form of attack, it should provide reasonable protection against those that a typical individual would easily be able to carry out.

Size, Cost, and Power Consumption

The electronics and batteries to power them must be small enough to fit into a container along with the pills. Furthermore, the batteries must be able to power the electronics for the entire duration of a prescription, which is assumed to last no longer than 30 days. The entire device must have a low cost.

Programmability

The prescribed interval between drug releases varies depending on the patient and the drug being used. Thus the prescribed interval should be programmable either at the pharmacy or at the drug manufacturer. It may be desireable not to allow prescirbed intervals less than some minimum in order to prevent an error in programming the prescribed interval to allow a patient to take the drug too frequently.

Electronics Design

Actuators activate the mechanisms to release a pill and to destroy the pills in the case of tampering. Sensors detect when a pill is taken and if the conainer is tampered with. A microcontroller controls the actuators and reads the sensors. Batteries power the whole system. Figure 1 below shows a schematic of the design.

The microcontroller controls the sensors and actuators. A microcontroller was chosen rather than a custom chip because the microcontroller offers a low-cost, low-power solution to make flexible designs for a prototype. Once the design is proven and tested in the field the microcontroller can be replaced by a custom chip, but designing such a chip would be too costly in terms of design time and startup costs.

A number of designs will work for the control software, pill release hardware, tamper sensors, and pill destruct actuator. The following sections describe designs for each of the components.

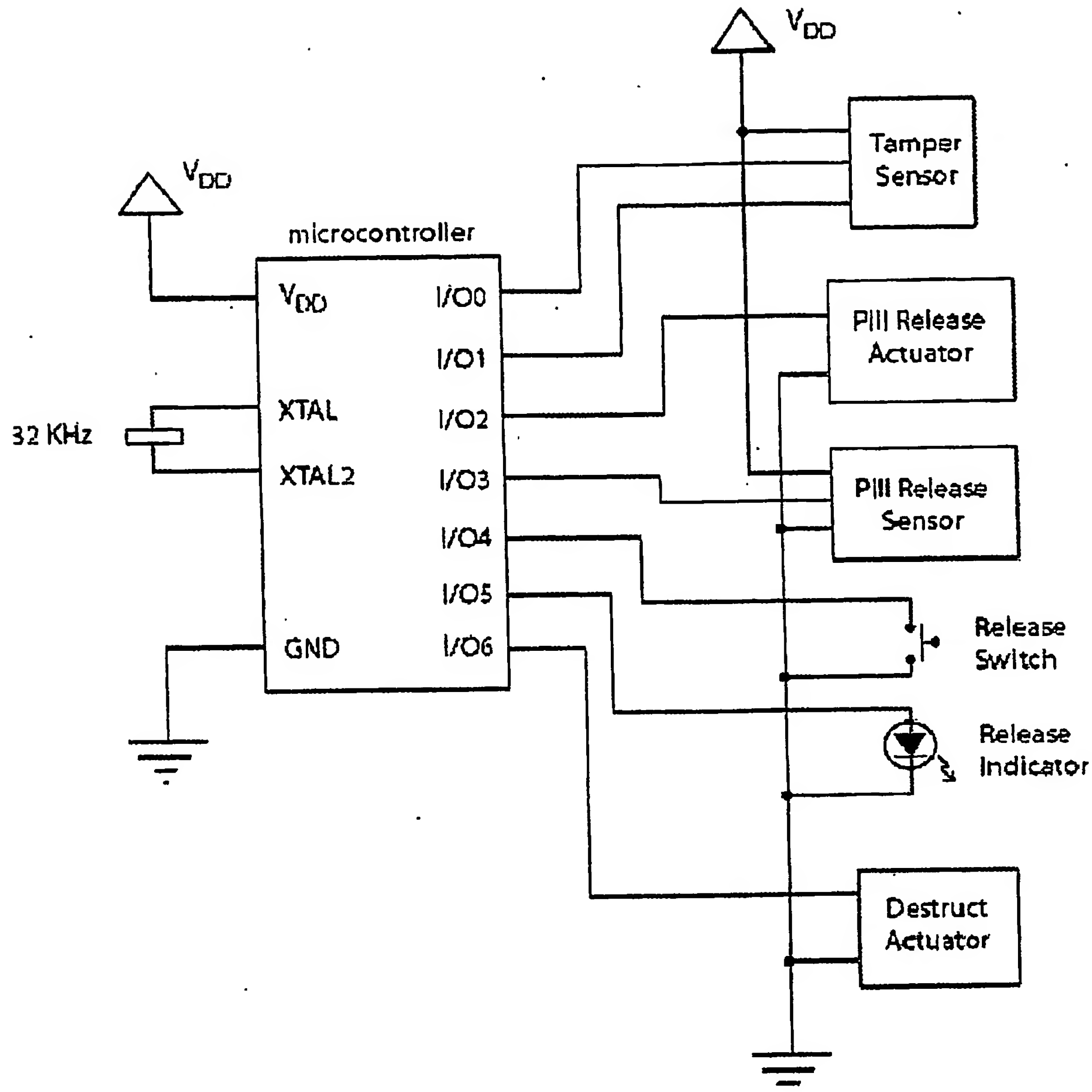


Figure 1: Schematic of the container electronics.

Pill Delivery

The prescribed rate given by the physician determines how often a patient should take pills. The patient, however, may be preoccupied or forget to take pills at exactly the prescribed rate. The container should limit the rate at which the patient takes pills, but allow the flexibility to take pills after their regularly scheduled release times.

The simplest algorithm for scheduling pill releases is to divide time into fixed *windows* and allow one pill to be taken within each window. For example, if the prescription

calls for one pill every six hours, the controller would measure six hour intervals and allow one release in each interval as shown in the figure below.

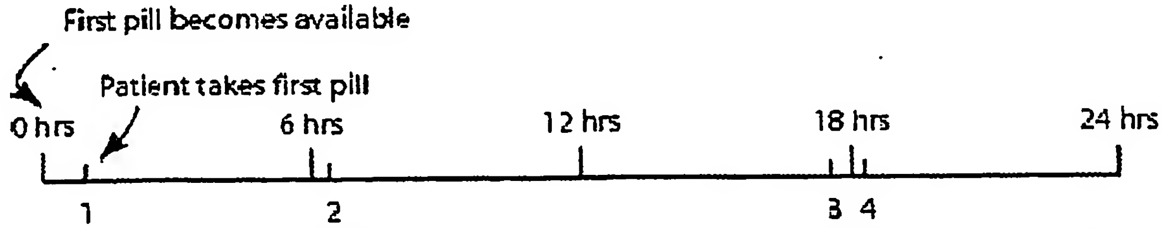


Figure 2: Fixed-window pill release schedule with a six hour interval. A pill is available four times per day in every six hour window. The patient can take the pill at any time during the window.

In the figure, tall lines show when pills become available. Short lines indicate times when a patient takes a pill. The patient can take a pill once during each window. As shown in the diagram above, the patient can take two pills in close succession, even though the average rate is limited to one pill every six hours. The patient will only be allowed one pill per window even if he or she does not take a pill during a previous window.

A fixed inter-pill release time prevents the patient from ever taking pills faster than the prescribed rate. The *inter-pill release time,* or time between pill releases is set to the prescribed interval. Figure 2, below, shows a possible fixed inter-pill release schedule assuming a prescribed rate of one pill every six hours. With this algorithm each pill is available six hours after the previous pill was taken.

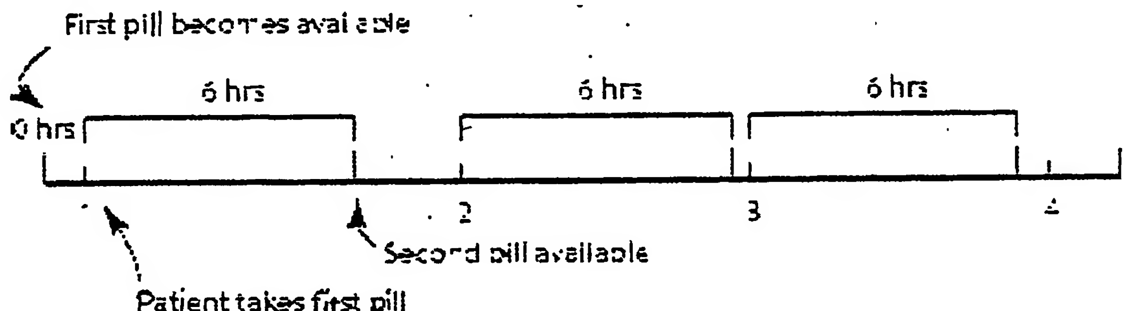


Figure 3: Fixed inter-pill release schedule with a six hour interval. Each pill is available six hours after the previous one is released. Delaying taking a pill does not allow the user to take two pills in a quick succession.

Though the fixed inter-pill release algorithm prevents taking two pills in close succession, it may be inconvenient for patients. The time of day at which a patient takes a pill will progressively get later if the patient consistently takes a pill after the inter-pill release time. For example, assume the patient wants to take a pill at 10 PM before going to bed and the prescription calls for one pill every six hours. If the patient takes the pill at 10:02 PM the first night, the earliest the patient can take the evening pill the next night would be 10:02 PM. If any of the other pills are taken after the minimum six hour inter-pill release time the evening pill will be delayed even more. Over time, the

evening pill could be pushed later and later at night. The only way for the patient to get back on schedule is to skip a pill.

Separating the minimum inter-pill release time from the prescribed interval is one way to avoid the time at which a patient can take a pill getting progrssively later, while still preventing the patient from taking several pills in close succession. The *flexible pill release* algorithm keeps track of the previous pill release time, a minimum pill release time which is shorter than the prescribed interval, and the prescribed interval. The flexible pill release algorithm is easiest to explain with an example.

Figure 4 demonstrates how the flexible pill release algorithm works. Assume the presribed interval is six hours and the minimum release time is five hours 45 minutes. The container starts keeping track of time when the patient takes the first pill. The second pill is released five hours 45 minutes after the first pill is taken. If the user takes the second pill after the prescribed interval of six hours, the next pill will be released five hours 45 minutes after the first pill. That is, the next prescribed interval begins immediately after the pill is taken.

In the example the user takes the third pill after it is released, but before the prescribed interval. In this case, the next prescribed interval will begin at the end of the current prescribed interval. The patient will not be able to take a pill until the minimum pill release time passes after the end of the current prescribed interval, rather than after the time at which the pill is taken.

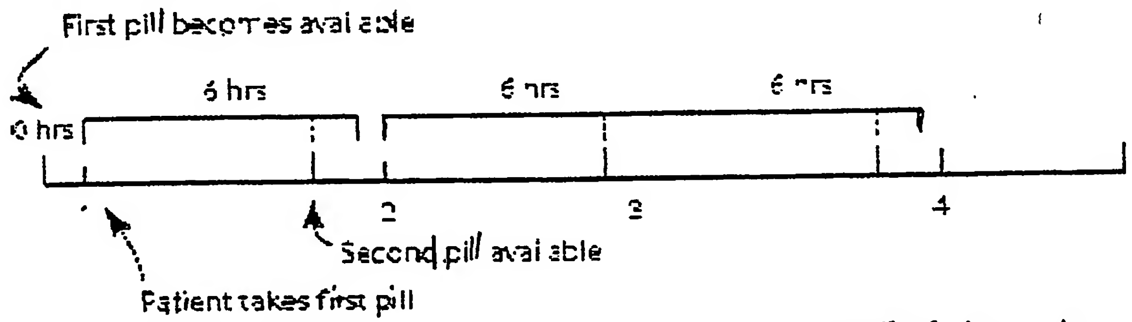


Figure 4: Separate minimum pill-release time and prescribed time. As with the fixed inter-pill release algorithm the patient may take a pill any time after the prescribed time. The patient may take a pill a small amount of time before the prescribed time, but the device will schedule the next prescribed pill release based on the prescribed time rather than the time the pill was taken.

In general when the minimum release time passes after the previous pill release time, the user can take a pill if the previous pill was taken after the prescribed interval. If the user takes a pill before the prescribed interval, the next pill will not be released until the minimum release time after the end of the previous prescribed interval. Though the patient

The fixed inter-pill release time prevents the user from taking two pills in short succession, but could force progressively later pill releases if the patient does not take a pill as soon as it is available. The separate pill-release time and prescribed time still prevents taking two pills in a short amount of time, while giving the patient more flexibility to take pills when convenient.

Tamper Sensor Options

The most important features of the tamper sensor are that it should be difficult to fool and use very little power. The two most promising designs are either a conductive sensor or a capacitive sensor.

Conductive Loop Tamper Sensor

With a conductive sensor, the container is wrapped with a thin conductor. One end of the conductor connects to ground, the other connects to an input pin and to VDD through a pull-up resistor. The input pin is programmed to cause an interrupt on a change. When the conductor is intact the input pin will read low. The conductor is designed to break if the container is broken or cut. When the conductive loop is broken, causing an open circuit, the pull-up resistor will pull the microcontroller input pin high causing an interrupt.

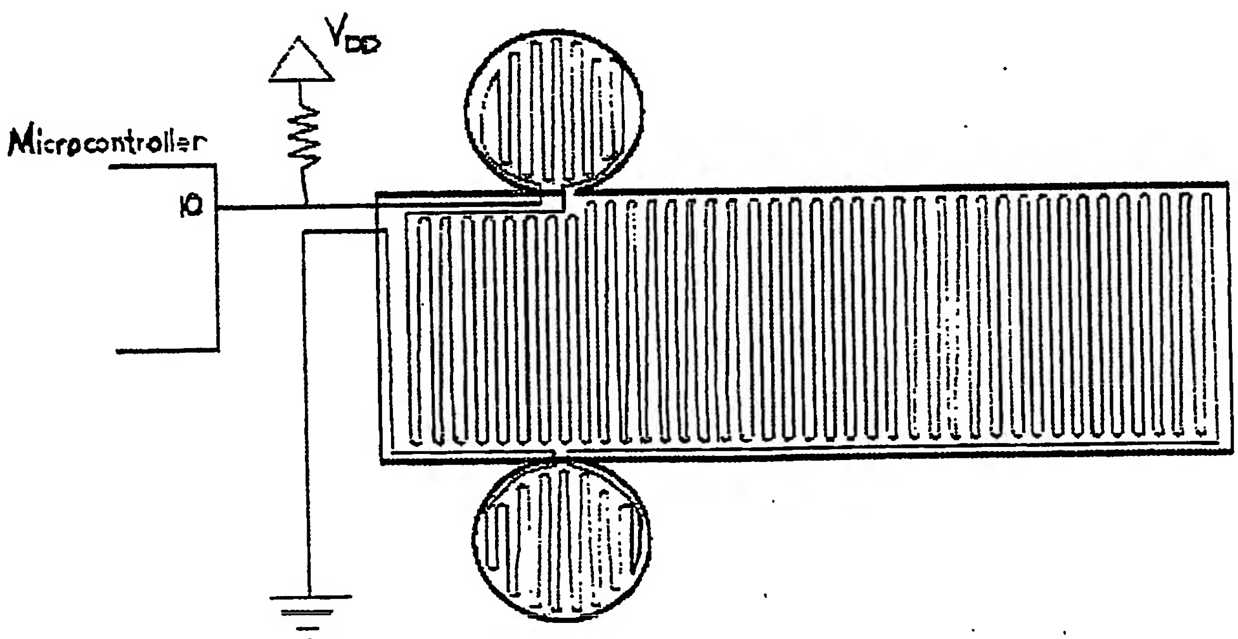


Figure 5: Schematic diagram for a conductive loop sensor connected to the microcontroller. The loop is shown as a label that could be applied to a cylindrical bottle.

The conductive loop could be implemented with thin wire wound around the container,

as a conductive pattern printed on paper, or as an etched pattern on a copper layer on the bottle. Regarless of how the sensor is implemented, the width of the conductor and the spacing between conductors must not exceed the width of a pill. The conductors should be weak enough that careful manipulation cannot open a hole without breaking at least one conductor.

Straightforward attempts to crush, cut, or drill through a container with the conductive sensor will break the connection. A careful attacker may be able to melt the container or carefully remove the container without breaking the conductors. To make attempts to break into the container difficult the conductors should be as delicate as possible. Wrapping such thin wires around the container may be difficult, but a conductor printed on paper would be difficult to manipulate without tearing.

An attacker may be able to bypass the conductive sensor by connecting a conductor to two points on the sensor. The microcontroller would not be able to determine if the conductor is broken between the two connection points. Making a reliable connection to a thin conductor, especially one printed on paper, would be difficult to do reliably. A complex wiring patter, such as a space filling curve, may be able to obfuscate the wiring pattern enough to make bypassing impractical.

An additional advantage of using a conductive sensor is that it might be used as an inductive loop antenna. The pharmacist could use the antenna interface to program the prescribed interval using a PC. If used as an antenna, the system would need to be tested to make sure that electromagentic noise from consumer devices do not accidently trigger the sensor.

One drawback of the conductive loop sensor is it requires tying a pull-up resistor between power and ground, such that current is always flowing through the resistor. This additional current drain could shorten the battery's life. It may be possible to reduce power consumption by using the microcontroller to power down the sensor part of the time.

Pressure Sensitive Tamper Sensor

A pressure sensitive tamper sensor would consist of two layers of conductive foil separated by a small space. If the container is crushed or cut the two layers will touch each other causing a short circuit. When the microcontroller detects a short circuit it can actuate the pill-destruct mechanism. The container must be rigid enough that casual contact will not deform it enough to trigger the pill-descruct mechanism.

The pressure sensitive sensor does a good job detecting attacks, like crushing and metling, that deform the container. A careful cut to the right place by a non-conductive tool, however, may be able to avoid causing a short circuit. Moreover, a careful attacker may be able to peel away the outer layer without touching the inner layer.

The main advantage of the pressure sensitive sensor is that it uses no current unless it detects tampering, improving battery life. It may be difficult to manufacture the sensor reliably such that the two layers always touch when disturbed, but never touch when not disturbed.

Capacitive Tamper Sensor

A capacitive sensor could be made using two layers of conductive foil separated by an insulator. The capacitance depends on the spacing of the two layers, and the shape of the container. The microcontroller can measure the capacitance and compare it with the initial capacitance when the system was started. Should the container change shape due to crushing, cutting, or any other attack, the capacitance will change and the microcontroller can actuate the pill destruct mechanism.

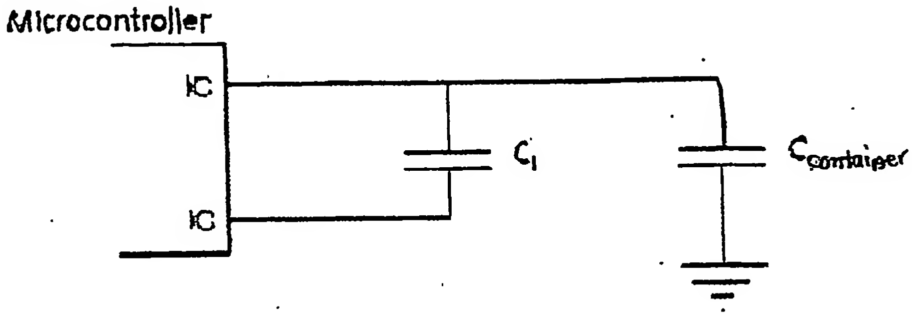


Figure 6: A schematic for a capactive sensor. $C_{container}$ is the capacitance of the container, C_1 is a known capacitance. The microcontroller repeatedly charges $C_{container}$ and distributes the charge between C_1 and $C_{container}$. The number of charge-discharge cycles required to make the voltage on C_1 reach a certain threshold is proportional to the capacitance of $C_{container}$.

The capacitive sensor does not require a DC path between power and ground, but it does require the CPU to be active to measure the capacitance of the conatiner. Initial calculations show the current requirement should be lower than the conductive sensor, but a prototype would give a better indication of the amount of power required. The capacitive sensor may also be sensitive to changes in temperature, as long as the changes happen slowly enough the microcontroller can be programmed to ignore them.

Other Attacks

Even with a tamper sensor the system could be vulnerable to other attacks. These attacks are difficult to guard against, but fortunately also more difficult to successfully carry out.

Electronic components are only rated for specific temperature ranges. In particular batteries deliver less current at colder temperatures. An attacker could use exterme cold to disable the battery. Many batteries are rated temperatures below the coldest setting on consumer freezers. Special equipment or liquid nitrogen or a similar fluid could be used to cool the system below its operating temperature, but such equipment are not readily found.

On the other end of the scale, an attacker could use heat to attempt to damage the microcontroller or to activate a nitnol based actuator. Temperatures high enough to damage the electronics may also damage the pills. If a nitinol actuators are used for the destruct mechanism as well as the dispensing mechansim, heat activating one should activate the other as well.

An electromagnetic pulse, from a microwave oven for example, could also damage the electronics, disabling the microcontroller. The conductive layers around a system with a capacitive sensor or a pressure sensor may be enough to shield the system. A conductive sensor may be vulerable to electromagnetic attacks becuse it behaves like an antenna.

Pill Release Actuator and Display

The container has a rotating cap to ensure that only one pill can be removed at a time. An actuator, such as a nitinol wire rotates the cap. The wire contracts when the microcontroller passes current through it. When no current passes through the wire a spring pulls the cap back into position. Depending on the mechanism available to move pills from the bottle to the cap, the cap might also need a sensor to detect whether a pill is present before rotating the cap. If the patient presses the button before the container is ready to release a pill, an LED indicator will blink to tell the patient to wait. The components placed in the cap are shown in Figure 7 below.

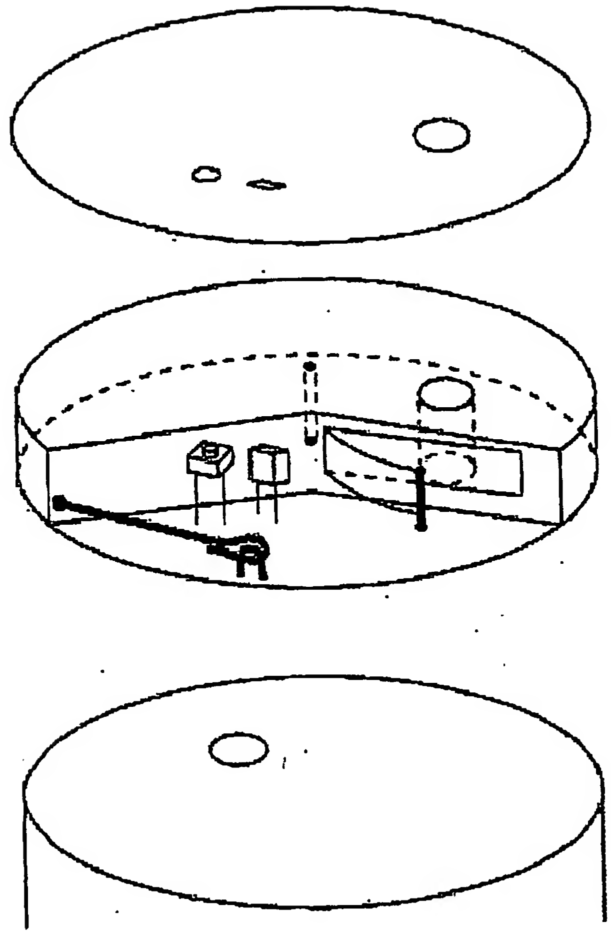
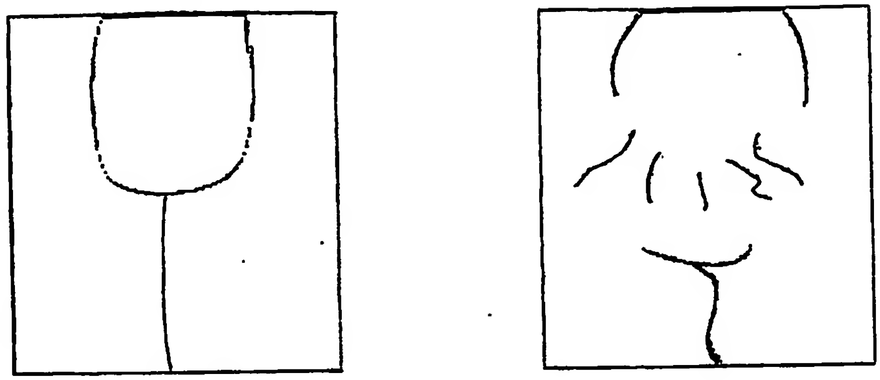


Figure 7: A diagram showing components in the cap. A nitinol wire connected to the cap causes it to rotate under microcontroller control. A spring pulls the cap back into place when no current flows through the wire. The button a patient presses to request a pill and the LED indicator are also shown.

Destruct

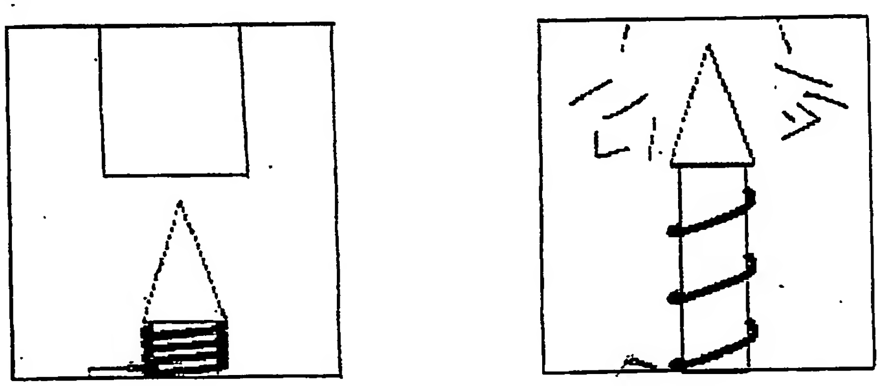
If the microcontroller detects tampering, it must render the pills inactive by releasing a solvent. One simple method would be to store the solvent in a small plastic bag inside the bottle. A nitinol wire could be connected to the bag. When the microcontroller detects tampering, it drives current through the wire causing it to contract and break the bag, as shown in Figure 8 below.



(a) Before Destruction (b) After Destruction

Figure 8: Plastic bag-based pill destruct mechanism.

A disadvantage of the bag design is that the solvent may not cover all the pills if the bottle is upside down. One way to correct this problem would be to destroy the vessel containing the solvent with more force. Breaking a vessel with a solenoid would take a fair amount of current. It would require less power to have a spring held back by a pin, which can be pulled free by an actuator, as shown below in Figure 9.



(a) Before Destruction (b) After Destruction

Figure 9: Spring-based pill destruct mechanism.

Another possibility would be to ignite some explosives, which either directly destroy the pills or spread the chemicals that do. Dye packs used with money use a similar method. Using explosives in a consumer device may have some safety concerns.

Programmability

The prescribed interval between drug releases varies depending on the patient and the drug being used. The interval only needs to be programmed into the device at the

pharmacy or factory where the bottle is filled. During programming, the tamper sensor is not used, so the I/O pins reserved for the sensor can be used for a two wire serial interface.

Batteries

The electronics need to be powered by batteries. The precise amount of energy required by the system depends on the type of sensor used. At worst, 3 AAA batteries will provide sufficient energy to last 30 days of normal operation. More likely a single 3 V or 3.6 V lithium battery will be sufficient.

Pill Safe

Mechanical Description and Conceptual Drawings

The mechanical design of the pill container is intended to be similar in size to currently used prescription bottles or only slightly larger. The container is anticipated to fit in a purse or briefcase to be transported easily by the user. The container will allow the user to rotate a lever or cap to release the pill at the scheduled time, but it will remain locked until that time.

The physical container is composed of a rigid exterior shell, the electronics and tamper detection system, a pill advancer, and an internal pill chamber. The outer shell provides a sealed container with only one opening where the pill is released. The pill advancer could be either a lever through the side of the container or a ring that rotates around the exterior shell. The pill advancer is designed to release a single pill at the prescribed time. The pill advancer will not advance if a pill is not in the advancer; a mechanical or electronic check will be present and will stop the advancer when a pill is not present. The advancer is locked in place by a mechanical pin that is controlled by the electronics system. The pin will by default lock the advancer in the release position and will unlock only after the prescribed amount of time has passed. The pin will operate similarly to the cocking mechanism on a gun and will "fire" back into the locked position when a pill is released. The cocking system will help to prolong the life of the power source because the electronic release will only consume power for the short period of time required to cock the mechanism.

The vial or internal pill chamber is where the pills will be stored and it is divided into two halves. The lower half is where the pills will be and has a small chute to direct the pills toward the pill advancer. The upper half is where the solvent will be located so that it can be released directly into the pill chamber if the pill safe detects the user tampering with the device. The release of the solvent will occur rapidly because the solvent will be under pressure from a spring and plunger assembly. This will help to ensure that the solvent will reach all the pills before the device is compromised.

The chute and cap are designed to protect the inner workings of the pill safe by having a 90° angle in the chute so that a user cannot reach the vial or pill advancer with a straight object. The chute and cap are designed with sloped surfaces to aid in the release of the pill.

434-293P

Tamper Detection Systems:

1. Electronic detection – Conductive Loop, Pressure Sensitive Sensor, Capacitive Sensor – (these methods are discussed in the electronics write-up)

2. Pressurize Container
   Description:
   The intention of the pressurized concept is that if the device is tampered with (broken, drill, cut, burned, or breached in any way) the higher internal pressure will be released and it will equalize with the atmospheric pressure. When the pressure drops the solvent will be released from the bladder in a mechanical, not an electrical process, perhaps a bladder with a trap door, a spring-loaded bladder, or a pressurized bladder. The concept of using a pressurized container is intended to remove the requirement of an electrical system to detect a breach or tampering with the pill safe, as well as the release the solvent to destroy the pills. The electrical system will be required to keep track of the time in order to provide the patient a pill at the prescribed time. At the appropriate time the electrical system will be required to unlock the pill safe and release a pill to the patient (whether the release is done by the electronics system, or the patient rotates a lever or pushes a tray). The electrical system must also be able to sense the removal of the pill from the device at which point the timer will reset and the device will be locked until the prescribed time has passed again.

   The pressurized device presents some difficulties, but these should be able to be easily overcome. One issue is pressure bleed off as pills are released, assuming that the release mechanism is properly designed and well sealed, a small amount of air will always be released with each pill. Over the span of a month this bleed off might reduce the pressure to a point that is near the critical threshold. One way of overcoming this is to use an internal piston that is spring-loaded to maintain a constant, or near constant, pressure over the time span of a month. This piston could also remove the possibility of premature release of the solvent as the container undergoes large temperature fluctuations that change the internal pressure of the device.

Solvent Release Mechanisms: (1-4 are discussed in the electronics write-up)

1. Nitinol Wire
2. Solenoid Pin
3. Solenoid Valve
4. Explosive charge

5. Heating Element
   Description:
   The concept of using a heating element is such that a wire or heating element will be placed against the bladder (and the bladder will be pressurized, perhaps by a spring) and the electrical system will short circuit the element when a breach is detected. The heat from the element will rupture the bladder and the solvent will be released. This method of solvent release does have the disadvantage of requiring a large source of power.

6. Pressurized Solvent Bladder/Pressurized Container
   Description:
   The pressurized solvent bladder (PSB) will work in conjunction with a pressurized pill container. The PSB could be similar to a paintball, in that it will be designed to be a thin-skinned bladder that will rupture easily. The PSB will be pressurized such that in normal atmospheric pressure it will explode due to the high internal pressure and release the solvent. The PSB system will require no integration of an electrical system to sense a container breach or solvent release.

7. Spring Loaded Bladder/Pressurized Container
   Description:
   The spring loaded bladder (SLB) will also work only with a pressurized container and not require an electrical system. The SLB can be thought of acting similar to a piston sliding within a cylinder, where the bladder is incorporated into the piston. The internal pressure from the pill container will act on one face of the piston/bladder and a spring (and sealed chamber or chamber vented to atmosphere) will act on the other face of the piston/bladder. When the pill container is under pressure, the piston/bladder will be held in position away from a bladder rupturing device, such as a sharp pin and jagged edge. When the pill container is breached and the pressure is released, the SLB will advance into the rupturing device and the solvent will be released.

8. Bladder Trap Door/Pressurized Container
   Description:
   The bladder trap door (BTD) is somewhat similar to the spring loaded bladder except that the trap door is all that moves in the STD device instead of the entire piston/bladder in the SLB device. The trap door will be held closed by the internal pressure of the pill container and will open when the pressure is released and the solvent will also be released.

Pill Release Mechanisms:

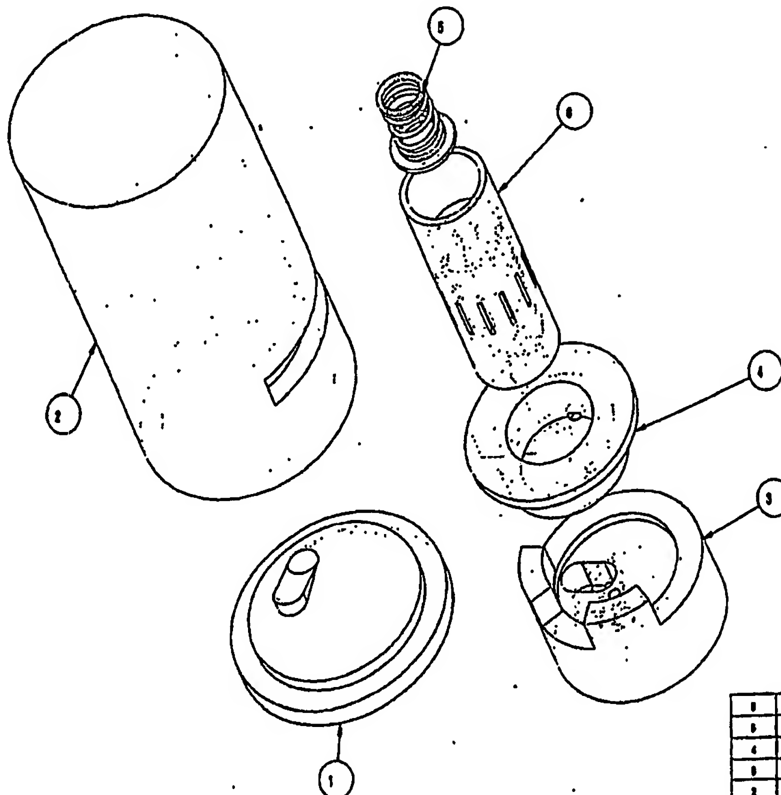
1. "PEZ" Dispenser – all the pills will be in a spring loaded tube and will require an escapement mechanism to release one pill at a time, such as the "cash register drawer" or rotational pill advancer

2. "Cash Register Drawer" – similar to a drawer in that it will slide in and out of the pill container and release one pill at a time to the patient. The drawer could be spring loaded and the user must push the drawer back into the pill container to reset the timer and tell the electronics system that a pill was removed. The system would require the electronics to keep time and release a lock on the drawer at the correct time. This system would have the possible disadvantage of releasing a pill after the correct time, but the patient is not ready for it, such as releasing a pill while the container is in a purse or if the device were on a table, a child or pet could get the pill and take it if the patient was unaware of the release.

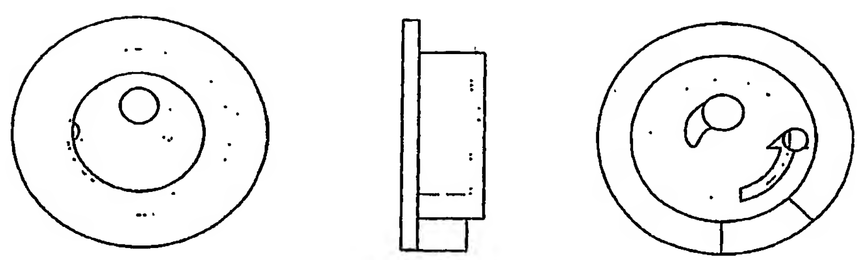
3. Rotational Pill Advancer – similar to the drawer concept but uses rotation for the escapement mechanism instead of linear motion. Requires the electronics system to

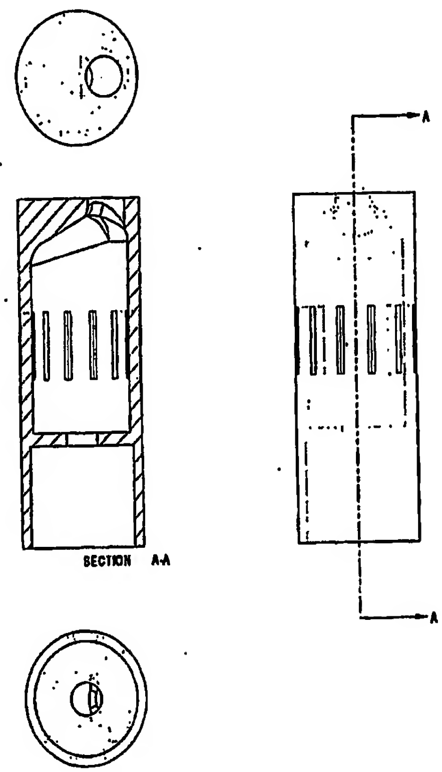
keep time and unlock the advancer at the correct time. The patient must rotate the mechanism to release a pill.

4. "Archimedes Screw" – another escapement mechanism to advance the pills using a screw or auger.



DET	QTY	NAME	MATERIAL	DESCRIPTION
6	1	VIAL		
5	1	SPRING		
4	1	PILL_ADVANCER		
3	1	CHUTE		
2	1	CASING		
1	1	CAP		





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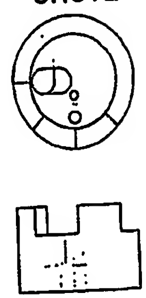
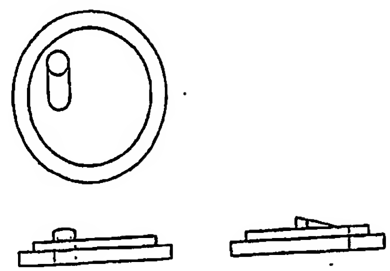
CHUTE



CAP



SPRING